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| 09/828,322 | 04/05/2001 | Laurent Schaller | P0021814.00 | 5639 |
| 77218 | 7590 | 02/17/2009 | EXAMINER | |
| Medtronic CardioVascular 7000 Central Avenue Minneapolis, MN 54432 | | | PATEL, NIHIL B | |
| | | ART UNIT | | PAPER NUMBER |
| | | 3772 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/828,322 | SCHALLER ET AL. |
| | Examiner | Art Unit |
| | NIHIR PATEL | 3772 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 December 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-26 and 31-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 31-38 is/are allowed.

6) Claim(s) 1-20, 24-26, 39-44, 47, 51, 54 and 55 is/are rejected.

7) Claim(s) 21-23, 45, 46, 52 and 53 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Response to Amendment

1. The amendment filed on December 8th, 2008 is acknowledged by the examiner. The amendment comprises amending claims 1, 3, 20, 24, 41, 43, 48 and 55 and cancelling claims 27-30.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims **1-19, 39 and 40** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 contains subject matter (**"at least one of the two clips is a self closing clip"**) which was not described in the specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims **1-6, 20, 24-26, 39-43, 47, 48-50, 54 and 55** are rejected under 35 U.S.C. 102(b) as being anticipated by Sander (US 5,374,268).

6. **As to claim 1**, Sander teaches a device and method for repairing torn tissue that comprises two clips **14** (see figure 1; see column 3 lines 50-60), each sized and shaped to attach tissues and hold the tissues together therein (see column 5 lines 5-20), wherein at least one of the two clips is a self closing clip adapted to self-transition from a first shape to a second shape, the first and second shape being different (see col. 4 lines 60-67; the Sander's reference states that "During arthroscopic surgery, as best seen by FIG. 5, the surgeon will approach the torn meniscus from in front of the knee and insert the two needles into the meniscus. As the needles are pushed through the meniscus to draw the edges of the tear together"; the phrase "to draw the edges of the tear together" implies that inherently the clips are self closing and as they are self closing they are drawing the edges of the tear together; the fact that when the shape of the device changes from a first shape to a second shape after being inserted implies that the shapes are different) and bridge portion **16** connecting the two clips and spacing the clips from one another (see figure 1; see column 3 lines 55-65).

7. **As to claim 2**, Sander teaches an apparatus wherein the bridge portion is substantially straight (the material used to manufacture the bridge portion is flexible and therefore is substantially straight).

8. **As to claim 3**, Sander teaches an apparatus wherein each of the two clips has an open configuration and a closed configuration independent of an other of the two clips (when the Sander's is in closed position, the clips **14** are close together and when the clips are in the open position the clips are spread apart).

9. **As to claim 4,** Sander teaches an apparatus wherein the bridge portion provides a predetermined spacing between the clips in the closed configuration (**see figure 4**).
10. **As to claim 5,** Sander teaches an apparatus wherein each clip has a proximal end point and a distal end point and wherein the proximal end point is separated from the distal end point when the clip is in open configuration (**before insertion**) and wherein the distance between the proximal end point and the distal end point is reduced when the clip is in the closed configuration (**once inserted; see figures 1 and 5**).
11. **As to claim 6,** Sander teaches an apparatus wherein the self-closing clip comprises shape memory material (**the bridge portion is flexible and there for has shape memory material**).
12. **As to claim 39,** Sander teaches an apparatus wherein each of the clips has a memory set loop configuration and a deformed configuration, and the bridge portion separates the loops from one another when the clips are in their memory set configuration (**see figures 1 and 4**).
13. **As to claim 40,** Sander teaches an apparatus wherein each of the clips has a free end (**see figure 1**).
14. **As to claim 20,** Sander teaches a device and method for repairing torn tissue that comprises a surgical fastener comprising two clips 14 (**see figure 1 and column 3 lines 50-60**); and shaped to attach tissues and hold the tissue therein including at least one self-closing clip having an open configuration and a closed configuration (**see figure 4**), where the closed configuration is an unbiased configuration having a loop shape and the open configuration is a biased configuration having a shape differing from a shape of the closed configuration (**the fact that when the shape of the device changes from a first shape to a second shape after being inserted implies that the shapes are different**), and a bridge portion 16 (**see figure 1 and see**

column 3 lines 50-60) having a substantially straight portion connecting the two clips (**the material used to manufacture the bridge portion is flexible and therefore is substantially straight**); and a release mechanism (**the bridge portion is also defined as a release mechanism**) having a first position to bias the self-closing clip in the open configuration, and a second position to unbias the self-closing into the closed configuration (**see figures 1 and 4**).

15. **As to claim 24**, Sander a device and method for repairing torn tissue that comprises a surgical fastener having two ends including a first end and a second end (**see figure 1**) and including two clips (**see column 3 lines 45-55**) sized and shaped to attach tissues including at least one self-locking clip having a loop shape terminating at the first end (**in Sander's reference both clips are self closing when they are inserted in the tissue**), and a substantially straight bridge portion **16** (**see figure 1 and column 3 lines 50-60**) connecting the two clips; and two tissue piercing members including a first tissue piercing member **13** releasably coupled to the first end and a second tissue piercing member releasably coupled to the second end (**see figure 1**).

16. **As to claim 25**, Sander teaches an apparatus that further comprises a release mechanism (**the bridge portion is also defined as a release mechanism**), and wherein the release mechanism activates the release of the two piercing members from the respective two ends (**see figures 1 and 4**).

17. **As to claim 26**, Sander teaches an apparatus wherein the release mechanism activates the closing of the self-closing clip (**see figures 1 and 4**).

18. **As to claim 41**, Sander teaches a device and method for repairing torn tissue that comprises an elongated member having a first loop shaped portion adapted to hold tissue therein

(**see figure 2**), a second loop shaped portion adapted to hold tissue therein (**see figure 2**), and a bridge portion **16** (**see figure 2**) bridging the first and second loop shaped portions (**see figure 2**), each loop shaped portion having a free end being deformable into a second deformed shape and self-tending to return from the second deformed shape towards the loop shape (**see figures 2 and 6; the fact that when the shape of the device changes from a first shape to a second shape after being inserted implies that the shapes are different**).

19. **As to claim 42**, Sander teaches an apparatus wherein the elongated members are not coils (**see figure 2**).

20. **As to claim 43**, Sander teaches an apparatus wherein the elongated member is a wire (**see figure 2**).

21. **As to claim 47**, Sander teaches an apparatus wherein the bridge portion **16** is substantially straight (**the material used to manufacture the bridge portion is flexible and therefore is substantially straight**).

22. **As to claim 48**, Sander teaches a device and method for repairing torn tissue that comprises an elongated member (**see figure 2**) having a first loop shaped portion, a second loop shaped portion (**see figure 2**) and a bridge portion **16** (**see figure 2**) bridging the first and second loop shaped portions (**see figure 4**), each loop shaped portion having a piercing element (**see figure 2**) at one end and a portion the merges into the bridge shaped portion, each loop shaped portion being deformable into a second deformed shape and having the property of tending to return towards its loop shape by moving upon itself (**see figures 1 and 4; the fact that when the shape of the device changes from a first shape to a second shape after being inserted implies that the shapes are different**).

23. **As to claim 49**, Sander teaches an apparatus wherein the elongated members are not coils (see figure 2).

24. **As to claim 50**, Sander teaches an apparatus wherein the elongated member is a wire (see figure 2).

25. **As to claim 54**, Sander teaches an apparatus wherein the bridge portion 16 is substantially straight (the material used to manufacture the bridge portion is flexible and therefore is substantially straight).

26. **As to claim 55**, Sander teaches a device and method for repairing torn tissue that comprises two clips 14 (see figures 1 and column 3 lines 45-55) and a bridge portion 16 (see figure 1 and column 3 lines 50-60) connecting the two clips (see figures 1) having a piercing element 13 (see figure 1) at one end thereof; each clip further self-transitioning (the fact that when the shape of the device changes from a first shape to a second shape after being inserted implies that the shapes are different and self transitioning) from an open configuration and a closed configuration, wherein each clip has proximal end point and a distal end point and wherein the proximal end point is separated from the distal end point when the clip is in the open configuration (before insertion) and wherein the distance between the proximal end point and the distal end point is reduced when the clip is in the closed configuration (once inserted; see figures 1 and 5).

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

29. Claims **44 and 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sander (US 5,374,268).

30. **As to claims 44 and 51**, Sander substantially teaches an apparatus; see rejection of claims 41 and 48, but does not disclose an apparatus wherein the wire is made from nitinol. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Sander's invention by providing a wire that is made from nitinol in order to make it safer for the patient, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Allowable Subject Matter

31. Claims **31-38** are allowed. The prior art does not disclose a pair of coils, one of the coils surrounding at least a portion of one of the first loop shaped portion and the other of the coils surrounding at least a portion of the second loop shaped portion.

32. Claims **7-19, 21-23, 45, 46, 52 and 53** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose a pair of coils, one of the coils surrounding at least a portion of one of the first loop shaped portion and the other of the coils surrounding at least a portion of the second loop shaped portion.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772